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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,101	11/08/2000	Gary D Glick	128019203801	2647

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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/700,101

Applicant(s)

GLICK ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23,130 and 131 is/are pending in the application.
- 4a) Of the above claim(s) 4,7,11,12,15-20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,8-10,13,14,21,23,130 and 131 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Election acknowledged***

1. Applicants' election with traverse the invention group I of claims 1-23 is acknowledged. Applicant also elect "psoriasis" as an elected species for the condition, and Bz-423 the elected compound where R1 is substituted with CH<sub>3</sub>; R2 with naphtyl; R3 with OH; and R4 with Chlorine). The restriction is made without traverse. Therefore, the restriction requirement is deemed to be proper and made FINAL.

### ***Status of Application***

1. Acknowledgement is made of amendment filed 1/4/06. Upon entering the amendment, the claims 5, 7 are amended and the claims 24-129 are canceled. New claims 130 and 131 are added.
2. The claims 1-23 and 130-131 are pending and presented for the examination.
3. The elected claims containing elected species, claims 1-3, 5-6, 8-10, 13-14, 21, 23 130 and 131 are presented for the examination. All remaining claims not drawn to the elected invention are withdrawn from further consideration as being non-elected.

### ***Allowable Subject Matter***

4. The following is a statement of reasons for the indication of allowable subject matter: the claimed invention(i.e. a method of treating psoriasis using a specific compound of benzodiazepine compound (elected species shown above)

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is allowable because the invention has not been taught or obvious over the prior art of the record. US4088756 teaches a psoriasis treatment using diazepam(see claim 1 and from col.12, lines 60 to col. 13, lines 11), however, it fails to teach the claimed comound(elected species, Bz-423). Since the elected species is patentably distinct and independent, the claims 130 and 131 is allowable.

Thus, the subject matter recited in claims 130 and 131 would be allowable if rewritten to overcome the rejection(s) by incorporating claims 130 and 131 into claim 1 to include all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 102/103***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-6, 8-10, 13-14, 21, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by, or alternatively under 35 U.S.C. 103(a) as being obvious over Voorhees(US 4088756).

The claims are drawn to a method of treating a condition(e.g. psoriasis) associated with dysregulation of the process of cell death using a benzodiazepine compound.

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US'756 teaches a psoriasis treatment using a composition comprising diazepam(a benzodiazepine compound), see claim 1 and abstract. Although the limitations recited in the dependent claims are not taught in same way, it would have been obvious as evidenced by the claims itself because the difference found in substitution on R2 position(Aliphatic group instead of hydrogen is also considered to be functionally equivalent when other substitution on different positions is learned). Thus, the modification is considered to be well within the skilled level of the ordinary skilled artisan and thus, the claims are not patentably distinct.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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8. Claims 1-3, 5-6, 8-10, 13-14, 21, 23 130 and 131 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/767283 and 10/886450. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims found in these applications relates to a method of treating psoriasis using benzodiazepine compound.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

1. No claim is allowed.
2. If claims 130 and 131 is incorporated into claim 1, the claims 1 and its dependent claims having substantially same or narrow scope will be considered to be allowable.

It is noted that claim 1 and its dependent claims are subject to 112, 1<sup>st</sup>(enablement) rejection, except claim 131 because the specification is only enabled for specific condition such as psoriasis but not all conditions that are associated with dysregulation of the process of cell death(e.g. possible different cancers, etc). Since the examination is performed to the extent that they read on use of the elected species in the claimed method, the 112, 1<sup>st</sup> rejection is in abeyance until further consideration for non-elected species is decided.

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**VICKIE KIM**  
**PRIMARY EXAMINER**

Vickie Kim  
April 3, 2006  
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